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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,545	03/28/2001	John kung	JBP0547	3384

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,545

Applicant(s)

KUNG ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-48 is/are pending in the application.
- 4a) Of the above claim(s) 47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 27-46 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that searching of all groups do not entail a burden upon the Patent and Trademark Office. This is not found persuasive because patent applicants are entitled to one invention per patent. Accordingly, a restriction requirement is proper when (a) the invention is independent or distinct as claimed; and (b) there is serious burden on the examiner if restriction is required. Further, appropriate explanation of separate classification, separate status in the art, or a different field of search are considered *prima facie* showing of a serious burden on the examiner. (see MPEP 803)

In the instant case, inventions are distinct as claimed, and there is serious burden on the examiner as the independent claims are classified in different field of search. Therefore, restriction as set forth in Paper No. 3 is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 47-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

This application contains claims 47-48 drawn to an invention nonelected with traverse in Paper No. 3. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Claims 27-46 are under consideration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-46 are provisionally rejected under the judicially created doctrine of double patenting over claims 24-25, 27-30, 34-37 of copending Application No.

09/341,426. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter. Further, they are both directed to compositions comprising non-ionic polymeric emulsifier, a sugar moiety and polyoxyethylene alcohol. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice one invention, once in possession of the other.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 41-46 and all dependent claims thereof are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41-46 respectively recite the limitations, "said hydrophobically modified acrylic acid" and said polyoxyalkylene." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27, 30-34, 38-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes et al US Patent 5,322,689.

The instant claims are directed to compositions comprising a hydrophobic or hydrophilic active agent, or a combination thereof and a polymeric emulsifier, and a method of use thereof.

Hughes et al disclose topical aromatic releasing compositions comprising an acrylic polymer (see col 3-4) a polyoxyethylene alcohol such as polyethylene glycol, or even polyhydroxy alcohol such as glycerin or propyl glycols or hexylene glycol (see col

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5, and col 7 lines 45-55), and various types hydrophilic and hydrophobic active moieties (see col 8-9, col 11 lines 30-65, claims 1-10). Hughes specifically discloses the use of such polymers as Pemulen (a hydrophobically-modified hydrophilic polymer)(see col 4, line 47; col 11, line 60). Hughes also discloses the use of Steareth-20 (see col 4, line 49). Hughes discloses the use of various thickening sugars including alkoxylated glucose (col 7, lines 50-54). Accordingly Hughes et al meet the limitations set forth in the instant claims.

5. Claims 27, 30-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al US patent 5,730,972.

The instant claims are directed to compositions comprising a hydrophobic or hydrophilic active agent, or a combination thereof, a sugar, and a polymeric emulsifier, and a method of use thereof.

Simon et al disclose compositions for combating skin marks comprising at least one sugar such as ascorbyl-2-glucoside, and a UVA screening agent (see abstract, claim 1 and 5). The composition of Simon et al also comprise a polymeric emulsifier such as Pemulen, a polyethylene alcohol such as polyethylene glycol stearate, and a moisturizing agent such as glycerol (see col 7-9; examples 2-4). Simon et al further disclose methods of using their composition for appropriate protection of skin. Therefore, Simon et al meet the limitations set forth in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 27-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froix et al US Patent 5,851,538, in view of Simon et al US Patent 5,730,972.

8. The instant claims are directed to compositions comprising a hydrophobic or hydrophilic active agent, or a combination thereof and a polymeric emulsifier. The instant compositions further comprise a sugar.

Froix et al teach topical skin formulations of Retinoid suspended in esters of acrylic or methacrylic polymers (see col 4 lines 14-25, claims 1, 5-10) in combination with antioxidants such as ascorbic acid (vitamin C) to lower the irritancy caused by retinoids when applied on skin (see example II, and claim 1-10). Froix et al however do not specifically use a sugar ester of ascorbic acid in their composition.

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The teachings of Simon et al are described above. Simon specifically states that ascorbic acid glucoside is highly water soluble and is converted to Vitamin C when administered to skin (see col 2, lines 51-60). Both Froix and Simon teach methods of enhancing topical delivery of active agents, therefore, their teachings are viewed as being in the same field of endeavor.

Although Froix does not use an ascorbic acid glycoside in his compositions, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Froix's composition by using an ascorbic acid precursor of Simon et al in place of vitamin C, because as stated by Simon, the ordinary skill in the art would have expected the ascorbic acid glycoside to convert to vitamin C. Further, Froix teaches that the combination of Vitamin C and retinoid together in a composition improves the skin irritation caused by retinoids, thus, the ordinary skill in the art would have had a reasonable expectation to reduce skin irritation of retinoids when administering it with any Vitamin C derivative. Accordingly, substituting Vitamin C with its art equivalent, ascorbic acid glycoside, would have been obvious.

Finally, absence of using unexpected results, optimizing the concentrations of individual ingredients is well within the scope of a skilled artisan, therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Froix composition to contain ascorbic acid glycoside, as taught by Simon, and further optimize the concentrations by routine experimentation for their respective pharmacological effects.

Conclusion

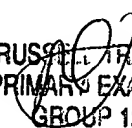
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

SS
November 27, 2002


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200